

**ASPIRIN- aspirin tablet, coated**  
**CVS Pharmacy**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**CVS 44-227**

**Active ingredient (in each tablet)**

Aspirin 325 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever

**Uses**

for the temporary relief of minor aches and pains or as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**

**Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if**

- stomach bleeding warning applies to you

- you have a history of stomach problems, such as heartburn
- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**

taking a prescription drug for

- gout
- diabetes
- arthritis

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- new symptoms occur
- pain gets worse or lasts more than 10 days
- redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

***Directions***

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours not to exceed 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use unless directed by a doctor

***Other information***

- store at 25°C (77°F); excursion permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients***

black iron oxide, cellulose, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, shellac wax, simethicone, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

**Questions or comments?**

**1-800-426-9391**

***Principal Display Panel***

♥ **CVS Health**

Compare to the active ingredient in Ecotrin®†

**Coated Tablets**

Regular Strength

Aspirin 325 mg

Pain reliever (NSAID)

Aspirin regimen\*\*

\*\*Talk to your doctor or other healthcare provider before using this product for your heart.

**125 ENTERIC COATED TABLETS**

Actual Size

Safety Coated

Package Contains

One Bottle

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

†This product is not manufactured or distributed by Medtech Products Inc., owner of the registered trademark Ecotrin®.

**Distributed by: CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

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50844 ORG031822757

No Print / No Varnish  
Lot no. & Exp. date



#140897  
TIMBER EVIDENT. DO NOT USE IF IMPRINTED  
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

B-0231-227-57-H  
ORG031822757

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

**Drug Facts**  
**Active ingredient (in each tablet)** Aspirin 325 mg (NSAID)  
**Purpose** Pain reliever  
**Uses** for the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide last relief of headaches or other symptoms needing immediate relief.  
**Warnings** Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, it changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.  
**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include: hives ■ block ■ facial swelling ■ asthma (wheezing)  
**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ are age 60 or older ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

**Drug Facts (continued)**  
**Do not use** ■ if you are allergic to aspirin or any other pain reliever/fever reducer ■ if you have ever had an allergic reaction to this product or any of its ingredients  
**Ask a doctor before use if** ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have asthma ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic  
**Ask a doctor or pharmacist before use if you are taking a prescription drug for** ■ gout ■ diabetes ■ arthritis  
**Stop use and ask a doctor if** ■ an allergic reaction occurs. Seek medical help right away. ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ ringing in the ears or a loss of hearing occurs ■ new symptoms occur ■ pain gets worse or lasts more than 10 days ■ redness or swelling is present  
These could be signs of a serious condition.  
**If pregnant or breast-feeding, ask a health professional before use.** It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Drug Facts (continued)**  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.  
**Directions** ■ drink a full glass of water with each dose ■ adults and children 12 years and over: take 1 to 2 tablets every 4 hours not to exceed 12 tablets in 24 hours unless directed by a doctor ■ children under 12 years: do not use unless directed by a doctor  
**Other information** ■ Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ see end flap for expiration date and lot number  
**Inactive ingredients** black iron oxide, cellulose, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #8 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, stibell wax, simethicone, sodium alginate, sodium bicarbonate, stearic acid, tac, titanium dioxide, triacetin, triethyl citrate  
**Questions or comments?** 1-800-426-9391  
This product is not manufactured or distributed by Medtch Products Inc., owner of the registered trademark Ecotrin®.  
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One CVS Drive, Woonsocket, RI 02895  
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50844 ORG031822757

CVS Health  
Coated Tablets  
**Aspirin 325 mg**  
Regular Strength  
Pain reliever (NSAID)  
125 ENTERIC COATED TABLETS

CVS Health  
Regular Strength  
**Aspirin 325 mg**  
Pain reliever (NSAID)  
Aspirin regimen\*\*  
\*\*Talk to your doctor or other healthcare provider before using this product for your heart.  
125 ENTERIC COATED TABLETS  
Actual Size Safety Coated  
Package Contains One Bottle  
Compare to the active ingredient in Ecotrin®  
Coated Tablets

CVS 44-227

**ASPIRIN**  
aspirin tablet, coated

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-927
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

### Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

### Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;227
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-927-57	1 in 1 CARTON	03/01/2019	
1		125 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-927-14	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	03/01/2019	

**Labeler** - CVS Pharmacy (062312574)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(69842-927)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(69842-927) , PACK(69842-927)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(69842-927)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(69842-927)

Revised: 2/2020

CVS Pharmacy